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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,813	12/04/2006	Thomas Stiefel	251508	9037

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EXAMINER	
GWARTNEY, ELIZABETH A	

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,813	STIEFEL, THOMAS	
	Examiner	Art Unit	
	Elizabeth Gwartney	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060530;20060424*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Here applicant has cancelled claims 9-13 and added 7 claims. It is assumed that claims 14-15 were cancelled as part of an amendment in the international phase. In response to this office action, a copy of the amended claims should be included.

Misnumbered claims 10-16 have been renumbered 16-22.

Claim Objections

2. Claim18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Here, claim 18 discloses amount of selenium and zinc broader than those disclosed in claim 16.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 21 recite the limitation "the trace elements". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1-6, 16 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Frankel ("Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations").

Regarding claims 1 and 4, Frankel discloses a total parenteral nutrition composition supplemented with trace elements including at least 50 meg/day (i.e. 0.05 mg/day) of selenium and/or 10 mg/day of zinc (p. 587/ paragraph 4, p. 588/paragraph 6). Frankel discloses that the parental administration of iron is problematic and does not indicate supplementation of iron in total parenteral nutrition compositions (p.583/paragraph 3, p. 589/paragraphs 4-5).

Regarding claims 2-3 and 5, Frankel discloses all of the claim limitations as set forth above. Given Frankel discloses a parenteral composition, it is clear that the composition is

inherently an infusion solution that exists as an aqueous solution and is suitable for parenteral administration.

Regarding claim 6, Frankel discloses all of the claim limitations as set forth above. Frankel also discloses total parenteral nutrition compositions comprising chromium and copper (p. 583/paragraphs 3-5, p. 584/paragraphs 1-9, p.585/paragraphs 1-4).

Regarding claims 16 and 19, Frankel discloses administering a total parenteral nutrition composition supplemented with 50 meg/day (i.e. 0.05 mg/day) of selenium and/or 10 mg/day of zinc to a human (p. 587/ paragraph 4, p. 588/paragraph 6). Frankel discloses that the parental administration of iron is problematic and does not indicate supplementation of iron in total parenteral nutrition compositions (p.583/paragraph 3, p. 589/paragraphs 4-5).

Regarding claim 18, Frankel discloses all of the claim limitations as set forth above. Frankel also discloses a total parenteral nutrition composition wherein the dose of selenium is as high as 250 meg (p.587/paragraph 5) and the does of zinc is 10 mg (p.588/paragraph 6).

Regarding claim 20, Frankel discloses all of the claim limitations as set forth above. Frankel also discloses administering a total parenteral nutrition composition further comprising chromium and/or copper (p. 583/paragraphs 3-5, p. 584/paragraphs 1-9, p.585/paragraphs 1-4).

Regarding claims 21-22, Frankel discloses all of the claim limitations as set forth above. Further, Frankel discloses that in some cases selenium supplemented compositions have been administered daily for 3-4 months (p.587/paragraph 5). Frankel also discloses that zinc supplemented compositions have been administered daily for 92 months (p.588/paragraph 6).

7. Claim 1, 4, 6, 16-17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ballevre et al. (US 2003/0161863).

Regarding claims 1 and 4, Ballevre et al. disclose an enteral nutrition composition comprising about 40 to about 100 μg /dose of selenium and 5 to 10 mg/dose of zinc (Abstract, [0029]-[0030]). Ballevre et al. discloses that the composition can be administered once per day or more than once per day depending on the needs of the patient ([0050]). Ballevre et al. discloses an enteral nutrition composition that does not comprise iron (*see* Example 1-[0048]-[0050]).

Regarding claim 6, Ballevre et al. disclose all of the claim limitations as set forth above. Ballevre et al. also disclose an enteral nutrition composition comprising trace elements selected from the group consisting of copper, chromium, molybedenum, manganese and iodine (Claims 6-8).

Regarding claim 16, Ballevre et al. disclose a method of providing an enteral nutrition composition to a patient, i.e. human, comprising the administering of a composition containing 50 μg /dose of selenium and 6 mg/dose of zinc (Abstract, [0029]-[0030], Example 1 – [0049]). Ballevre et al. discloses an enteral nutrition composition that does not comprise iron (*see* Example 1-[0048]-[0050]).

Regarding claim 17, Ballevre et al. disclose all of the claim limitations as set forth above. Further, Ballevre et al. disclose that the enteral nutrition compositions are administered to critically ill patients including those with sepsis ([0005], [0011]).

Regarding claim 20, Ballevre et al. disclose all of the claim limitations as set forth above. Ballevre et al. also disclose administering an enteral nutrition composition that contains a trace

element selected from the group consisting of copper, chromium, molybedenum, manganese and iodine (Claims 6-8).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel ("Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations").

Regarding claims 7-8, Frankel disclose all of the claim limitations as set forth above. While Frankel disclose a total parenteral nutrition composition containing selenium and zinc, the reference does not explicitly disclose that composition is formulated as a 10 ml infusion solution that exists as an aqueous solution in an ampoule.

It is well known to package parenteral compositions in parenteral containers, including an ampoule, vial or bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have packaged the total parenteral nutrition composition of Frankel in any parenteral container, including an ampoule, and arrived at the current invention.

Further, it would have been obvious to one of ordinary skill in the art to have formulated the total parenteral nutrition composition in any size of dose, including 10-ml, because change in size is not patently distinct over the prior art absent persuasive evidence that the particular configuration of the claimed invention is significant. See *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). MPEP 2144.04[R-1].

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel ("Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations") in view of Ballevre et al. (US 2003/0161863).

Regarding claim 17, Frankel discloses all of the claim limitations as set forth above. While Frankel disclose administering a total parenteral nutrition composition comprising selenium and zinc to a human, the reference does not explicitly disclose that the human is an intensive care patient or a sepsis patient.

Ballevre et al. teach an enteral nutrition composition comprising about 40 to about 100 μg /dose of selenium and 5 to 10 mg/dose of zinc (Abstract, [0029]-[0030]) that is administered to critically ill patients including those with sepsis ([0005], [0011]). Further, Ballevre et al.

discloses an enteral nutrition composition that does not comprise iron (*see* Example 1-[0048]-[0050]).

Given that Ballevre et al. teach that is was known to administer nutritional compositions comprising selenium and zinc to critically ill patients including those with sepsis, since Ballevre et al. teach a composition identical to that of Frankel and that presently claimed, it would have been obvious to one of ordinary skill in the art to have administered the total parenteral nutrition composition of Frankel to critically ill patients including those with sepsis.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Sommerville et al. (US 6,391,332) teaches an enteral nutritional composition that contains 15-60 mg of zinc and 70-120 micrograms of selenium. The reference does not teach a nutritional composition suitable for parenteral administration.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday;7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794